Remarks/Arguments

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claims 1, 2, 4, 9, 14-16, 19, 25, 27, 28, 37-39, 51, 52, 59, 66 and 68-78 are pending. Claim 54 has been canceled without prejudice.

Claims 1, 2, 4, 9, 14-16, 19, 25, 27, 28, 37, 39, 51, 52, 54, 68, 69, 70, 72 and 73 stand rejected and claims 76-78 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Sayler et al. (U.S. Patent No. 6,673,596; filed Dec. 2, 1999). Reconsideration is requested.

Sayler is directed to a sensor that can be implanted in the body of an animal. The sensor is a complex bioluminescent bioreporter integrated circuit (BBIC) that produces a luminescent response when exposed to a target substance, such as glucose, glucagons or insulin. An integrated circuit detects the emitted bioluminescence, processes the resulting signal, and reports the results.

The Sayler patent describes three membranes, namely a semi-permeable membrane 21, a protective coating 24, and an optional "selectively permeable membrane" depicted in Fig. 10C. The BBIC described in this document **requires** the presence of a "semi-permeable membrane 21" between the cells in container 22 and the body in which the sensor is implanted. The semi-permeable membrane 21 (shown in Fig. 2 of Sayler) is needed in order to prevent fluorescent substances from the reporter system from entering the body, because these substances are toxic to a human body. Thus, this membrane protects the body tissue. The protective coating 24 is positioned inside the BBIC and does not contact the outer surface of the BBIC housing 20. The third membrane, the "optional membrane" of Fig. 10C, is depicted as fully encompassing the bioreporter on four sides as a separate membrane from membrane 21. More specifically, the optional membrane allows the transport of small molecules such as glucose and insulin into the bioreporter and prohibits the influx of immune effector cells and antibodies (col. 31, lines 33-37). Thus, the membrane of 10C is positioned inside the container 22 and functions to protect the cells in the bioreporter.

Matrigel can be used inside the compartment 22 to coat the bioreporter. The Matrigel is used as a glue to promote attachment of epithelial cells or to suspend the cells. The Matrigel is not in contact with the outer surface of the BBIC and is not in contact with the biological tissue in which is sensor is implanted.

Column 17, lines 48-67 of Sayler discuss biocompatible coverings for implants and prosthetic devices. Coverings that are mentioned include (1) a thin biocompatible carbon film, (2) a three-dimensionally woven or knitted fabric of organic fibers, (3) a collagen coating, and (4) an albumin coating. Furthermore, three patents are referenced, namely U.S. Patent Nos. 5,653,755, 5,779,734 and 5,814,091. U.S. Patent Nos. 5,653,755 and 5,779,734 describe implant coverings made from fluoropolymer filaments attached to a stretch fabric backing. U.S. Patent No. 5,814,091 describes a two layer capsule for a medical implant comprising a first layer of a biocompatible material such as titanium and a second layer of a substantially diffusion-proof and corrosion-resistant metal. Col. 25, lines 14-26 of Sayler describes encapsulation of the BBIC in a mesh-reinforced polymer bag. None of the coating materials described Sayler or in the three cited patents constitute a matrix supporting cells.

Independent claims 37 and 78 of the present patent application provide that the matrix that contacts the outer surface of the implant **comprises basement membrane**. The Sayler reference clearly does not disclose or suggest the subject matter of independent claims 37 and 78 of the present application, which both recite that (a) the biocompatible matrix material comprises basement membrane, (b) the basement membrane is in contact with an outer surface of an implantable device.

Another important distinction of the claimed system over Sayler is that the cells in the matrix of the system as recited in independent claims 1, 28, 37 and 78 enhance or increases the lifespan of the implantable device. The only materials mentioned in Sayler (at col. 17, lines 62-67 of Sayler) as promoting biocompatibility between the implant and the body are collagen and albumin, as well as the materials mentioned in the above-cited patent references, none of which constitutes "cells." Matrigel is used in

Sayler as a glue inside the device to support cells in compartment 22, not to enhance lifespan in the manner claimed in the subject application.

As recited in claim 37 of the present application, the biological matrix material comprising basement membrane **and/or** the cellular community increase the lifespan of the device. Collagen and albumin are not "basement membrane" and do not have "cells" supported by the matrix.

Thus, claims 1, 2, 4, 9, 14-16, 19, 25, 27, 28, 37, 39, 51, 52, 68, 69, 70, 72, 73 and 76-78 are not anticipated by Sayler. Reconsideration is requested.

Claims 28, 37, 38, 59, 66, 70, 71 and 74 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sayler et al. (U.S. Patent No. 6,673,596; filed Dec. 2, 1999), in view of Soykan et al. (U.S. Patent Application Publication No. 2001/0000802; effective filing date: Dec. 20, 2000). Reconsideration is requested.

The Soykan Patent describes an implantable system for drug delivery to treat a disease, not to promote compatibility of an implant with body tissue. The Office Action indicates that the Soykan reference is cited for its disclosure endothelial cells that line the walls of blood vessels and that secrete vasodilatory, thrombolytic or angiogenic factors, such as vascular endothelial growth factor (VEGF). This document does not make up for the above-noted deficiencies of Sayler in that it does not disclose a cell-containing matrix on the outer surface of an implantable device that is configured to enhance the lifespan of the implantable device. Furthermore, this document does not disclose a matrix comprising a basement membrane. Thus, claims 28, 37, 38, 59, 66, 70, 71 and 74 are not obvious over the combination of Sayler and Soykan. Reconsideration is requested.

In view of the above, it is believed that this application is in condition for allowance, and such a Notice is respectfully solicited.

Respectfully submitted,

Ulrike W. Klueh et al.

By: Diane F. Covello
Diane F. Covello
Registration No. 34,164
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: December 9, 2009
750 Main Street, Suite 1400
Hartford, CT 06103-2721
Telephone: 860-527-9211
Our Ref: MTT/101/PC/US
DFC/eg

G:\AYR saved docs\Filing Docs\MTT\mtt101pcus\mtt101pcusResponse120909.doc